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10/584,477	06/23/2006	Thomas Hille	RO4283US (#90568)	3321
7590 03/21/2008 D. Peter Hochberg Co., L.P.A. The Baker Building 6th Floor 1940 East 6th Street Cleveland, OH 44114-2294				
EXAMINER				
HAWTHORNE, OPHELIA ALTHEA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,477

Applicant(s)

HILLE ET AL.

Examiner

OPHELIA HAWTHORNE

Art Unit

4148

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 15 & 23 - 31 is/are rejected.
- 7) ☒ Claim(s) 16 - 22 & 32 - 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 23 June 2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1 – 6, & 23 - 26** are rejected under 35 U.S.C. 102(b) as being anticipated by **Yamazaki et al. (EP 0 338 173 A1)**.

Regarding claim 1, Yamazaki et al. discloses a wound dressing ([Page 2], line 54) for covering bleeding wounds, said wound dressing being a ready-made product and comprising a carrier material containing a compound selected from the group consisting of adrenaline ([Page 3], line 43) and one of the pharmaceutically acceptable salts of adrenaline ([Page 3], line 44), wherein said compound is a vasoconstrictive medicinal substance ([Page 3], line 43).

Regarding claim 2, Yamazaki et al. discloses wherein characterized in that the carrier material contains at least one further vasoconstrictive medicinal substance selected from the group consisting of the sympathomimetics ([Page 3], line 43).

Regarding claim 3, Yamazaki et al. discloses wherein any the carrier material further contains, at least one substance selected from the group consisting of an astringent substance and or/and a haemostatic substance ([Page 3], line 42).

Regarding claim 4, Yamazaki et al. discloses wherein the carrier material contains at least one further active substance for promoting wound healing but having no vasoconstrictive effect ([Page 3], line 40).

Regarding claim 5, Yamazaki et al. discloses wherein at least one further active substance is selected from the group consisting of amino acids, peptides, enzymes, lymphokines, coagulation factors, anti-inflammatory substances, vitamins, polysaccharides and skin caring substances ([Page 3], lines 40 – 42).

Regarding claim 6, Yamazaki et al. discloses wherein the carrier material is selected from the group consisting of wovens, interlaced yarns, crocheted fabrics, knit fabrics, nonwovens, papers, absorbent gauze, wadding, compresses, and combinations ([Page 5], lines 6 – 10).

Regarding claim 23 Yamazaki et al. discloses use of a wound dressing ([Page 2], line 54) for treating bleeding wounds, by administering adrenaline ([Page 3], line 43) to bleeding wounds the bleeding to stop the bleeding.

Regarding claim 24, Yamazaki et al. discloses use of a vasoconstrictive medicinal substance ([Page 3], line 43) for producing the production of a ready-made wound dressing or an adhesive wound dressing for treating the treatment of bleeding wounds, by using wherein adrenaline ([Page 3], line 43) or one of the pharmaceutically acceptable salts of adrenaline ([Page 3], line 44), as the medicinal substance.

Regarding claim 25 Yamazaki et al. discloses wherein said amino acids are glycine ([Page 3], line 40).

Regarding claim 26, Yamazaki et al. discloses wherein the carrier material is selected from the group consisting of cotton fabrics, viscose fabrics, cotton- viscose blended fabrics, synthetic fibre wovens, synthetic fibre nonwovens, cotton wadding, viscose wadding, and gauze-wadding compresses ([Page 5], lines 6 – 10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Shanbrom Pub No. (US 2006/0142684 A1)**.

Regarding claim 7, Yamazaki et al. discloses all of the claimed limitations above except wherein the carrier material has a low peroxide content.

However, Shanbrom teaches an apparatus with a sponge containing more than one percent by weight hydrogen peroxide ([Page 3], claim 2).

Given the teachings of Shanbrom, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with a carrier material having low peroxide content. Doing so would enhance oxygen levels within the wound, prevent infection and speed wound healing.

6. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Cullen et al. Pub No. (US 2007/0148214 A1)**.

Regarding claim 8, Yamazaki et al. discloses all of the claimed limitations above except wherein the carrier material contains at least one additive selected from the group comprising consisting of disinfectants, antioxidants, preservatives and moisture-absorbing substances.

However, Cullen et al. teaches wound dressing material comprising of antioxidants **([PARA], 0056)**.

Given the teachings of Cullen et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with a carrier material comprising of antioxidants. Doing so would remove reactive oxygen species from the wound dressing.

7. **Claims 9 – 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Heinecke et al. (US 6,685,682 B1)** and further in view of **Cullen et al. Pub No. (US 2007/0148214 A1)**.

Regarding claim 9, Yamazaki et al. discloses a wound dressing for covering bleeding wounds **([Page 2], line 54)**, comprising an active substance-containing carrier material containing a compound selected from the group consisting of adrenaline **([Page 3], line 43)** and one of the pharmaceutically acceptable salts of adrenaline **([Page 3], line 44)**.

Yamazaki et al. fails to disclose an adhesive wound dressing having a backing layer connected with the carrier material, and a detachable protective layer.

However, Heinecke et al. teaches an adhesive wound dressing comprising a backing layer and a detachable protective liner **([Col. 16], claim 1)**.

Given the teachings of Heinecke et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with an adhesive wound dressing comprising a backing layer and a detachable protective liner. Doing so would provide a smooth application of the dressing to the patient's skin.

Yamazaki et al., in view of Heinecke et al., fails to disclose the surface area of the backing layer being larger than the surface area of the carrier material, and wherein an adhesive surface comprises the surface area of the backing layer which projects beyond the surface area of the carrier material.

However, Cullen et al. teaches a wound dressing comprising a backing layer being larger than the active layer **(PARA, [0065])**.

Given the teachings of Cullen et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing

for topical administration of drugs to wounds and burns of Yamazaki et al. modified by Heinecke et al. with the surface area of the backing layer being larger than the surface area of the carrier material and with an adhesive surface comprising the surface area of the backing layer which projects beyond the surface area of the carrier material. Doing so would provide proper adhesion of the wound dressing to the user's skin.

Regarding claim 10, Yamazaki et al. in view of Heinecke et al. fails to disclose the adhesive surface of the backing layer projects beyond the carrier material on all sides to form an adhesive margin.

However, Cullen et al. teaches an adhesive surface of the backing layer projects beyond the carrier material on all sides to form an adhesive margin (**PARA, [0065]**).

Given the teachings of Cullen et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al., modified by Heinecke et al. with an adhesive surface of the backing layer that projects beyond the carrier material on all sides to form an adhesive margin. Doing so would provide proper adhesion of the wound dressing to the user's skin.

Regarding claim 11, Yamazaki et al., in view of Heinecke et al., fails to disclose the backing layer comprising materials selected from the group consisting of a rigid material, a flexible material, an elastic material, and a composite material comprising at least a rigid, flexible and elastic material.

However, Cullen et al. teaches a wound dressing with a backing layer made from polyurethanes (**PARA, [0067]**).

Given the teachings of Cullen et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al., modified by Heinecke et al. with a backing layer comprising of materials selected from the group consisting of a rigid material, a flexible material, an elastic material and a composite material comprising at least a rigid, flexible and elastic materials. Doing so would provide the passage of water vapor to be transmitted to the wound under the dressing which would heal under moist conditions, without causing the skin surrounding the wound to macerate.

Regarding claim 12, Yamazaki et al., in view of Heinecke et al., fails to disclose a pressure-sensitive adhesive layer comprising a polymer matrix having at least one additive forms one of any said adhesive surface and said adhesive margin.

However, Cullen et al. teaches an adhesive wound dressing with a pressure-sensitive adhesive layer comprising a polymer matrix with at least one additive forms **(PARA, [0067 & 0068])**.

Given the teachings of Cullen et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al., modified by Heinecke et al. with a pressure-sensitive adhesive layer comprising a polymer matrix with at least one additive forms, one of any adhesive surface and adhesive margin. Doing so would ensure the cohesiveness of the wound dressing.

Regarding claim 13, Yamazaki et al., in view of Heinecke et al., fails to disclose the polymer matrix contains one of a pressure- sensitive adhesive base polymer and a combination of at least two pressure-sensitive adhesive base polymers, the polymer(s) being selected from the group consisting of natural rubber, synthetic rubber, poly(meth)acrylic acid, poly(meth)acrylates, poly(meth)acrylate copolymers and combinations of said polymers.

However, Cullen et al. teaches suitable polymers for forming a backing sheet which include poly alkoxyalkyl acrylates and methacrylates (**PARA, [0067]**).

Given the teachings of Cullen et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al., modified by Heinecke et al. with the polymer matrix containing one of the pressure- sensitive adhesive base polymer and a combination of at least two pressure-sensitive adhesive base polymers, the polymer(s) being selected from the group consisting of natural rubber, synthetic rubber, poly(meth)acrylic acid, poly(meth)acrylates, poly(meth)acrylate copolymers and combinations of said polymers. Doing so would ensure the cohesiveness of the wound dressing.

8. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Heinecke et al. (US 6,685,682 B1)** further in view of **Cullen et al. Pub No. (US 2007/0148214 A1)** and further in view of **Kanios (US 6,638,528 B1)**.

Regarding claim 14, Yamazaki et al., invention as modified by Heinecke et al. and Cullen et al., fails to disclose the polymer matrix containing at least one additive selected from the group consisting of plasticisers, tackifiers, stabilisers, carrier substances and fillers.

However, Kanios teaches a polymer matrix containing a tackifying resin ([Col. 31], line 44).

Given the teachings of Kanios, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al., modified by Heinecke et al. and Cullen et al. with a polymer matrix containing at least one additive selected from the group consisting of plasticisers, tackifiers, stabilisers, carrier substances and fillers. Doing so would ensure the cohesiveness of the wound dressing.

9. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (EP 0 338 173 A1) in view of Ubel et al. (US 6,981,590 B1).

Regarding claim 15, Yamazaki et al. fails to disclose an adhesive wound dressing singly packed in an oxygen-impervious packaging material and protected against the action of light.

However, Ubel et al. teaches an apparatus for storing moisture-sensitive products ([Col. 2], lines 40 - 42) consisting of folding patterns that reduces curing due to inadvertent exposure to ambient condition ([Col. 2], lines 48 - 50).

Given the teachings of Ubel et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical

administration of drugs to wounds and burns of Yamazaki et al. with an adhesive wound dressing singly packed in an oxygen-impervious packaging material and protected against the action of light since adrenaline is unstable in the presence of atmospheric oxygen.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Shanbrom Pub No. (US 2006/0142684 A1)**.

Regarding claim 27, Yamazaki et al. fails to disclose wherein the carrier material has a low peroxide content not exceeding the value 10.

However, Shanbrom teaches an apparatus with a sponge containing more than one percent by weight hydrogen peroxide (**[Page 3], claim 2**).

Given the teachings of Shanbrom, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with a carrier material having a low peroxide content not exceeding the value 10. Doing so would enhanced oxygen levels within the wound, prevent infection and speed wound healing.

11. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Reidenberg et al. Pub No. (US 2008/0026042 A1)**.

Regarding claim 28, Yamazaki et al. fails to disclose the material selected from the group consisting of metal foil and plastic film.

However, Reidenberg et al. teaches materials suitable for making backing layer comprising of metal foils and polymer films (**PARA, [0038]**).

Given the teachings of Reidenberg et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with a material selected from a group consisting of metal foil and plastic film. Doing so would provide functional support to the wound dressing.

12. **Claims 29 & 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Iskanderova et al. (US 5,683,757)**.

Regarding claim 29, Yamazaki et al. fails to disclose wherein said material is a metallised polymer film.

However, Iskanderova et al. teaches a substrate selected from a group of polymers comprising metallised polymer films (**[Col. 8], lines 23 - 24**).

Given the teachings of Iskanderova et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with a material that is metallised polymer film. Doing so would provide plastics with high strength that are compatible with the skin.

Regarding claim 30, Yamazaki et al. fails to disclose wherein said metallised polymer film is a polymer film metallised with aluminum.

However, Iskanderova et al. teaches a substrate selected from a group of polymers comprising metallised polymer films with a layer of aluminum ([Col. 8], lines 31 - 32).

Given the teachings of Iskanderova et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with a material that is metallised polymer film with aluminum. Doing so would provide plastics with high strength that are compatible with the skin.

13. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yamazaki et al. (EP 0 338 173 A1)** in view of **Ubel et al. (US 6,981,590 B1)**.

Regarding claim 31, Yamazaki et al. fails to disclose an adhesive wound dressing singly packed in an oxygen-impervious packaging material and protected against the action of light.

However, Ubel et al. teaches an apparatus for storing moisture- sensitive products ([Col. 2], lines 40 - 42) consisting of folding patterns that reduces curing due to inadvertent exposure to ambient condition ([Col. 2], lines 48 - 50).

Given the teachings of Ubel et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify an ionic dressing for topical administration of drugs to wounds and burns of Yamazaki et al. with an adhesive wound dressing singly packed in an oxygen-impervious packaging material and protected against the action of light since adrenaline is unstable in the presence of atmospheric oxygen.

Allowable Subject Matter

14. **Claims 16 – 22 & 32 - 37** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is (571) 270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 4148

/Ophelia Hawthorne/
Examiner, Art Unit 4148

/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4148